

117TH CONGRESS  
2D SESSION

# H. R. 5657

---

IN THE SENATE OF THE UNITED STATES

APRIL 5, 2022

Received

---

## AN ACT

To amend the Controlled Substances Act to make marijuana accessible for use by qualified marijuana researchers for medical purposes, and for other purposes.

1       *Be it enacted by the Senate and House of Representa-*  
2       *tives of the United States of America in Congress assembled,*

1     **SECTION 1. SHORT TITLE.**

2         This Act may be cited as the “Medical Marijuana Re-  
3     search Act”.

4     **SEC. 2. FACILITATING MARIJUANA RESEARCH.**

5         (a) PRODUCTION AND SUPPLY.—The Secretary of  
6     Health and Human Services—

7                 (1) until the date on which the Secretary deter-  
8     mines that manufacturers and distributors (other  
9     than the Federal Government) can ensure a suffi-  
10    cient supply of marijuana (as defined in section 102  
11    of the Controlled Substances Act (21 U.S.C. 802),  
12    as amended by section 8) intended for research by  
13    qualified marijuana researchers registered pursuant  
14    to paragraph (3) of section 303(f) of the Controlled  
15    Substances Act (21 U.S.C. 823(f)), as added by sec-  
16    tion 3, shall—

17                     (A) continue, through grants, contracts, or  
18     cooperative agreements, to produce marijuana  
19     through the National Institute on Drug Abuse  
20     Drug Supply Program;

21                     (B) not later than one year after the date  
22     of enactment of this Act, act jointly with the  
23     Attorney General of the United States to estab-  
24     lish and implement a specialized process for  
25     manufacturers and distributors, notwithstanding  
26     the registration requirements of sec-

1              tion 303 of such Act (21 U.S.C. 823), to supply  
2              qualified marijuana researchers with marijuana  
3              products—

4                  (i) available through State-authorized  
5                  marijuana programs; and

6                  (ii) consistent with the guidance  
7                  issued under subsection (c); and

8                  (C) not later than 60 days after the date  
9                  of enactment of this Act, jointly convene with  
10                 the Attorney General a meeting to initiate the  
11                 development of the specialized process described  
12                 in subparagraph (B); and

13                 (2) beyond the date specified in paragraph (1),  
14                 may, at the Secretary's discretion, continue—

15                 (A) through grants, contracts, or coopera-  
16                 tive agreements, to so produce marijuana; and

17                 (B) to implement such specialized process.

18                 (b) REQUIREMENT TO VERIFY REGISTRATION.—Be-  
19                 fore supplying marijuana to any person through the Na-  
20                 tional Institute on Drug Abuse Drug Supply Program or  
21                 through implementation of the specialized process estab-  
22                 lished under subsection (a)(1)(B), the Secretary of Health  
23                 and Human Services shall—

24                 (1) require the person to submit documentation  
25                 demonstrating that the person is a qualified mari-

1       juana researcher seeking to conduct research pursuant  
2       to section 303(f)(3) of the Controlled Substances  
3       Act, as added by subsection (d) of this section, or  
4       a manufacturer duly registered under section 303(l)  
5       of the Controlled Substances Act, as added by sec-  
6       tion 3 of this Act; and

7                   (2) not later than 60 days after receipt of such  
8       documentation, review such documentation and  
9       verify that the marijuana will be used for such re-  
10      search (and for no other purpose authorized pursu-  
11      ant to this Act or the amendments made by this  
12      Act).

13               (c) GUIDANCE ON USE OF STATE-AUTHORIZED  
14 MARIJUANA PROGRAMS.—Not later than 180 days after  
15 the date of the enactment of this Act, the Secretary of  
16 Health and Human Services shall issue guidance related  
17 to marijuana from State-authorized marijuana programs  
18 for research.

19               (d) RESEARCH.—Section 303(f) of the Controlled  
20 Substances Act (21 U.S.C. 823(f)) is amended—

21                   (1) by redesignating paragraphs (1) through  
22       (5) as subparagraphs (A) through (E), respectively;  
23                   (2) by striking “(f) The Attorney General” and  
24       inserting “(f)(1) The Attorney General”;

1                   (3) by striking “Registration applications” and  
2                   inserting the following:

3                   “(2) Registration applications”;

4                   (4) in paragraph (2), as so designated, by strik-  
5                   ing “schedule I” each place that term appears and  
6                   inserting “schedule I, except marijuana,”;

7                   (5) by striking “Article 7” and inserting the  
8                   following:

9                   “(4) Article 7”; and

10                  (6) by inserting before paragraph (4), as so  
11                  designated, the following:

12                  “(3)(A) The Attorney General shall register the ap-  
13                  plicant to conduct research with marijuana (including any  
14                  derivative, extract, preparation, and compound thereof) if,  
15                  irrespective of whether the applicant is registered pursu-  
16                  ant to paragraphs (1) and (2)—

17                  “(i) the applicant meets the requirements for  
18                  being registered under such paragraphs to dispense,  
19                  or conduct research with respect to, controlled sub-  
20                  stances in schedule I, II, III, IV, or V;

21                  “(ii) the applicant is compliant with, and au-  
22                  thorized to conduct the activities described in clause  
23                  (i) under, the laws of the State in which the appli-  
24                  cant practices; and

1           “(iii) in the case of an applicant pursuing clin-  
2       ical research, the applicant’s clinical research pro-  
3       tocol has been reviewed and authorized to proceed by  
4       the Secretary under section 505(i) of the Federal  
5       Food, Drug, and Cosmetic Act.

6           “(B) An applicant registered under subparagraph (A)  
7       shall be referred to in this section as a ‘qualified mari-  
8       juana researcher’.

9           “(C)(i) Not later than 60 days after the date on  
10      which the Attorney General receives a complete applica-  
11      tion for registration under this paragraph, the Attorney  
12      General shall approve or deny the application.

13          “(ii) For purposes of clause (i), an application shall  
14      be deemed complete when the applicant has submitted  
15      documentation showing that the requirements under sub-  
16      paragraph (A) are satisfied.

17          “(iii) In the case of a denial under clause (i), the At-  
18      torney General shall provide a written explanation of the  
19      basis for the denial.

20          “(D) The Attorney General shall grant an application  
21      for registration under this paragraph unless the Attorney  
22      General determines that the issuance of the registration  
23      would be inconsistent with the public interest. In deter-  
24      mining the public interest, the following factors shall be  
25      considered:

1               “(i) The applicant’s experience in dispensing, or  
2               conducting research with respect to, controlled sub-  
3               stances.

4               “(ii) The applicant’s conviction record under  
5               Federal or State laws relating to the manufacture,  
6               distribution, or dispensing of controlled substances.

7               “(iii) Compliance with applicable State or local  
8               laws relating to controlled substance misuse or diver-  
9               sion.

10               “(iv) Such other conduct which may threaten  
11               the public health and safety.

12               “(E)(i) A qualified marijuana researcher shall store  
13               marijuana to be used in research in a securely locked, sub-  
14               stantially constructed cabinet.

15               “(ii) Except as provided in clause (i), any security  
16               measures required by the Attorney General for applicants  
17               conducting research with marijuana pursuant to a reg-  
18               istration under this paragraph shall be consistent with the  
19               security measures for applicants conducting research on  
20               other controlled substances in schedule II that have a  
21               similar risk of diversion and abuse.

22               “(F)(i) If the Attorney General grants an application  
23               for registration under this paragraph, the applicant may  
24               amend or supplement the research protocol and proceed  
25               with the research under such amended or supplemented

1 protocol, without additional review or approval by the At-  
2 torney General or the Secretary of Health and Human  
3 Services if the applicant does not change the type of mari-  
4 juana (including any derivative, extract, preparation, and  
5 compound thereof), the source of the marijuana, or the  
6 conditions under which the marijuana is stored, tracked,  
7 or administered.

8       “(ii) If an applicant amends or supplements the re-  
9 search protocol or initiates research on a new research  
10 protocol under clause (i), the applicant shall, in order to  
11 renew the registration under this paragraph, provide no-  
12 tice to the Attorney General of the amended or supple-  
13 mented research protocol or any new research protocol in  
14 the applicant’s renewal materials.

15       “(iii)(I) If an applicant amends or supplements a re-  
16 search protocol and the amendment or supplement in-  
17 volves a change to the type of marijuana, the source of  
18 the marijuana, or conditions under which the marijuana  
19 is stored, tracked, or administered, the applicant shall pro-  
20 vide notice to the Attorney General not later than 30 days  
21 before proceeding on such amended or supplemental re-  
22 search or new research protocol, as the case may be.

23       “(II) If the Attorney General does not object during  
24 the 30-day period following a notification under subclause

1 (I), the applicant may proceed with the amended or sup-  
2 plemental research or new research protocol.

3 “(iv) The Attorney General may object to an amend-  
4 ed or supplemental protocol or a new research protocol  
5 under clause (i) or (iii) only if additional security meas-  
6 ures are needed to safeguard against diversion or abuse.

7 “(G) If marijuana is listed on a schedule other than  
8 schedule I, the provisions of paragraphs (1), (2), and (4)  
9 that apply to research with a controlled substance in the  
10 applicable schedule shall apply to research with marijuana  
11 or that compound, as applicable, in lieu of the provisions  
12 of subparagraphs (A) through (F) of this paragraph.

13 “(H) Nothing in this paragraph shall be construed  
14 as limiting the authority of the Secretary under section  
15 505(i) of the Federal Food, Drug, and Cosmetic Act or  
16 over requirements related to research protocols, including  
17 changes in—

18 “(i) the method of administration of marijuana;  
19 “(ii) the dosing of marijuana; and  
20 “(iii) the number of individuals or patients in-  
21 volved in research.”.

1   **SEC. 3. MANUFACTURE AND DISTRIBUTION OF MARIJUANA**

2                   **FOR USE IN LEGITIMATE RESEARCH.**

3         Section 303 of the Controlled Substances Act (21  
4 U.S.C. 823), as amended by section 2, is further amended  
5 by adding at the end the following:

6                 “(l) REGISTRATION OF PERSONS TO MANUFACTURE  
7 AND DISTRIBUTE MARIJUANA FOR USE IN LEGITIMATE  
8 RESEARCH.—

9                 “(1) REGISTRATION OF MANUFACTURERS.—

10                 “(A) IN GENERAL.—Beginning not later  
11 than the day that is 1 year after the date of en-  
12 actment of the Medical Marijuana Research  
13 Act, the Attorney General, pursuant to sub-  
14 section (f)(3) and subject to subparagraph (B)  
15 of this paragraph, shall register an applicant to  
16 manufacture marijuana (including any deriva-  
17 tive, extract, preparation, and compound there-  
18 of) that is intended for—

19                 “(i) use by qualified marijuana re-  
20 searchers for research pursuant to sub-  
21 section (f)(3); or

22                 “(ii) subsequent downstream manu-  
23 facture by a duly registered manufacturer  
24 for use by qualified marijuana researchers  
25 for research pursuant to subsection (f)(3).

1                 “(B) PUBLIC INTEREST.—The Attorney  
2 General shall register an applicant under sub-  
3 paragraph (A) unless the Attorney General de-  
4 termines that the issuance of such registration  
5 is inconsistent with the public interest. In deter-  
6 mining the public interest, the Attorney General  
7 shall take into consideration—

8                     “(i) maintenance of effective controls  
9 against diversion of marijuana and any  
10 controlled substance compounded there-  
11 from into other than legitimate medical,  
12 scientific, or research channels;

13                     “(ii) compliance with applicable State  
14 and local laws relating to controlled sub-  
15 stance misuse and diversion;

16                     “(iii) prior conviction record of the  
17 applicant under Federal or State laws re-  
18 lating to the manufacture, distribution, or  
19 dispensing of such substances; and

20                     “(iv) such other conduct which may  
21 threaten the public health and safety.

22                 “(2) REGISTRATION OF DISTRIBUTORS.—

23                     “(A) IN GENERAL.—Beginning not later  
24 than the day that is 1 year after the date of en-  
25 actment of the Medical Marijuana Research

1           Act, the Attorney General shall register an ap-  
2           plicant to distribute marijuana (including any  
3           derivative, extract, preparation, and compound  
4           thereof) that is intended for use by qualified  
5           marijuana researchers for research pursuant to  
6           subsection (f)(3) or intended for subsequent  
7           downstream manufacture by a duly registered  
8           manufacturer for use by qualified marijuana re-  
9           searchers for research pursuant to such sub-  
10           section, unless the Attorney General determines  
11           that the issuance of such registration is incon-  
12           sistent with the public interest.

13           “(B) PUBLIC INTEREST.—In determining  
14           the public interest under subparagraph (A), the  
15           Attorney General shall take into consider-  
16           ation—

17                 “(i) the factors specified in clauses (i),  
18                 (ii), (iii), and (iv) of paragraph (1)(B); and  
19                 “(ii) past experience in the distribu-  
20                 tion of controlled substances, and the exist-  
21                 ence of effective controls against diversion.

22           “(3) NO LIMIT ON NUMBER OF MANUFAC-  
23           TURERS AND DISTRIBUTORS.—Notwithstanding any  
24           other provision of law, the Attorney General shall  
25           not impose or implement any limit on the number of

1       persons eligible to be registered to manufacture or  
2       distribute marijuana pursuant to paragraph (1) or  
3       (2).

4                 “(4) REQUIREMENT TO VERIFY USE FOR LE-  
5       GITIMATE RESEARCH.—As a condition of regis-  
6       tration under this section to manufacture or distribute  
7       marijuana, the Attorney General shall require the  
8       registrant—

9                     “(A) to require any person to whom the  
10       marijuana will be supplied to submit docu-  
11       mentation demonstrating that the marijuana  
12       (including any derivative, extract, preparation,  
13       and compound thereof) will be used by qualified  
14       marijuana researchers for research pursuant to  
15       subsection (f)(3) or for subsequent downstream  
16       manufacture by a duly registered manufacturer  
17       for use by qualified marijuana researchers for  
18       research pursuant to such subsection;

19                     “(B) in the case of distribution, to com-  
20       plete, with respect to that distribution, the ap-  
21       propriate order form in accordance with section  
22       308 and to upload such forms to the system  
23       used by the Drug Enforcement Administration  
24       for such distribution;

1               “(C) to include in the labeling of any mari-  
2               juana so manufactured or distributed—

3                     “(i) the following statement: ‘This  
4               material is for biomedical and scientific re-  
5               search purposes only.’; and

6                     “(ii) the name of the requestor of the  
7               marijuana;

8               “(D) to limit the transfer and sale of any  
9               marijuana under this subsection—

10                   “(i) to researchers who are registered  
11               under this Act to conduct research with  
12               marijuana or to manufacturers duly reg-  
13               istered under this subsection; and

14                   “(ii) for purposes of use in preclinical  
15               research or in a clinical investigation pur-  
16               suant to an investigational new drug ex-  
17               emption under 505(i) of the Federal Food,  
18               Drug, and Cosmetic Act or for the pur-  
19               poses of further manufacturing of mari-  
20               juana; and

21               “(E) to transfer or sell any marijuana  
22               manufactured under this subsection only with  
23               prior, written consent for the transfer or sale by  
24               the Attorney General.

1               “(5) TIMING.—Not later than 60 days after re-  
2 ceipt of a request for registration under this sub-  
3 section to manufacture or distribute marijuana, the  
4 Attorney General shall—

5               “(A) grant or deny the request; and  
6               “(B) in the case of a denial, provide a  
7 written explanation of the basis for the denial.

8               “(6) DEEMED APPROVAL.—If the Attorney  
9 General fails to grant or deny a request for registra-  
10 tion under this subsection to manufacture or dis-  
11 tribute marijuana within the 60-day period referred  
12 to in paragraph (5), such request is deemed ap-  
13 proved.”.

14 **SEC. 4. TERMINATION OF INTERDISCIPLINARY REVIEW**  
15               **PROCESS FOR NON-NIH-FUNDED QUALIFIED**  
16               **MARIJUANA RESEARCHERS.**

17               The Secretary of Health and Human Services may  
18 not—

19               (1) reinstate the Public Health Service inter-  
20 disciplinary review process described in the guidance  
21 entitled “Guidance on Procedures for the Provision  
22 of Marijuana for Medical Research” (issued on May  
23 21, 1999); or

24               (2) create an additional review of scientific pro-  
25 tocols that is only conducted for research on mari-

1       juana other than the review of research protocols  
2       performed at the request of a qualified marijuana  
3       researcher conducting nonhuman research that is  
4       not federally funded, in accordance with section  
5       303(f)(3)(A) of the Controlled Substances Act, as  
6       added by section 2 of this Act.

7 **SEC. 5. CONSIDERATION OF RESULTS OF RESEARCH.**

8       Immediately upon the approval by the Food and  
9 Drug Administration of an application for a drug that  
10 contains marijuana (as defined in section 102 of the Con-  
11 trolled Substances Act (21 U.S.C. 802), as amended by  
12 section 8 of this Act) under section 505 of the Federal  
13 Food, Drug, and Cosmetic Act (21 U.S.C. 355), and (irre-  
14 spective of whether any such approval is granted) not later  
15 than the date that is 5 years after the date of enactment  
16 of this Act, the Secretary of Health and Human Services  
17 shall—

18              (1) conduct a review of existing medical and  
19              other research with respect to marijuana;  
20              (2) submit a report to the Congress on the re-  
21              sults of such review; and

22              (3) include in such report whether, taking into  
23              consideration the factors listed in section 201(c) of  
24              the Controlled Substances Act (21 U.S.C. 811(c)),  
25              as well as any potential for medical benefits, any

gaps in research, and any impacts of Federal restrictions and policy on research, marijuana should be transferred to a schedule other than schedule I (if marijuana has not been so transferred already).

5 SEC. 6. PRODUCTION QUOTAS FOR MARIJUANA GROWN  
6 FOR LEGITIMATE, SCIENTIFIC RESEARCH.

7 Section 306 of the Controlled Substances Act (21  
8 U.S.C. 826) is amended by adding at the end the fol-  
9 lowing:

10       “(j) The Attorney General may only establish a quota  
11 for production of marijuana that is manufactured and dis-  
12 tributed in accordance with the Medical Marijuana Re-  
13 search Act that meets the changing medical, scientific, and  
14 industrial needs for marijuana.”.

15 SEC. 7. ARTICLE 28 OF THE SINGLE CONVENTION ON NAR-  
16 COTIC DRUGS.

17 Article 28 of the Single Convention on Narcotic  
18 Drugs shall not be construed to prohibit, or impose addi-  
19 tional restrictions upon, research involving marijuana, or  
20 the manufacture, distribution, or dispensing of marijuana,  
21 that is conducted in accordance with the Controlled Sub-  
22 stances Act (21 U.S.C. 801 et seq.), this Act, and the  
23 amendments made by this Act.

1   **SEC. 8. DEFINITIONS.**

2       (a) **QUALIFIED MARIJUANA RESEARCHER.**—In this  
3   Act, the term “qualified marijuana researcher” has the  
4   meaning given the term in section 303(f)(3) of the Con-  
5   trolled Substances Act, as added by section 2(d) of this  
6   Act.

7       (b) **UPDATING TERM.**—Section 102(16) of the Con-  
8   trolled Substances Act (21 U.S.C. 802(16)) is amended—

9              (1) in subparagraph (A), by striking “the term  
10       ‘marihuana’ means” and inserting “the terms ‘mari-  
11       huana’ and ‘marijuana’ mean”; and

12              (2) in subparagraph (B), by striking “The term  
13       ‘marihuana’ does not” and inserting “The terms  
14       ‘marihuana’ and ‘marijuana’ do not”.

15   **SEC. 9. DETERMINATION OF BUDGETARY EFFECTS.**

16       The budgetary effects of this Act, for the purpose of  
17   complying with the Statutory Pay-As-You-Go Act of 2010,  
18   shall be determined by reference to the latest statement  
19   titled “Budgetary Effects of PAYGO Legislation” for this  
20   Act, submitted for printing in the Congressional Record  
21   by the Chairman of the House Budget Committee, pro-

1 vided that such statement has been submitted prior to the  
2 vote on passage.

Passed the House of Representatives April 4, 2022.

Attest:                    CHERYL L. JOHNSON,  
*Clerk.*